

**HIN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

HUMAN GENOME SCIENCES, INC.  
14200 Shady Grove Road  
Rockville, MD 20850

Plaintiff,

v.

Case No.: 10-cv-00575 (ESH)

DAVID J. KAPPOS, in his official capacity as  
Under Secretary of Commerce for Intellectual  
Property and Director of the United States Patent  
and Trademark Office

Office of the General Counsel  
United States Patent and Trademark Office  
P.O. Box 15667, Arlington, VA 22215

Defendant.

**FIRST AMENDED COMPLAINT**

Plaintiff Human Genome Sciences, Inc. ("HGS"), for its complaint against the Honorable David J. Kappos, states as follows:

**NATURE OF THE ACTION**

1. This is an action by the assignee of United States Patent Nos. 7,601,351 ("the '351 patent"), 7,605,236 ("the '236 patent"), 7,064,189 ("the '189 patent"), and 7,138,501 ("the '501 patent") seeking judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the '351 patent be changed from 1,497 days to 1,546 days, the patent term adjustment for the '236 patent be changed from 209 days to 478 days, or at least 416 days, the patent term adjustment for the '189 patent be changed from 271 days to 399 days, and the patent term adjustment for the '501 patent be changed from 754 days to 1,135 days.

**JURISDICTION AND VENUE**

2. This action arises under 35 U.S.C. § 154 and the Administrative Procedure Act, 5 U.S.C. §§ 701-706.

3. This Court has jurisdiction to hear this action and is authorized to issue the relief sought pursuant to 28 U.S.C. §§ 1331, 1338(a), 1361, 2201, and 2202, 35 U.S.C. § 154(b)(4)(A), and 5 U.S.C. §§ 701-706.

4. Venue is proper in this district by virtue of 35 U.S.C. § 154(b)(4)(A).

5. This Complaint is being timely filed in accordance with 35 U.S.C. § 154(b)(4)(A) and Fed. R. Civ. P. 6(a)(3) and alternatively, pursuant to the doctrine of equitable tolling and/or in compliance with the discovery rule.

**THE PARTIES**

6. Plaintiff HGS is a corporation, organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its principal place of business located at 14200 Shady Grove Road, Rockville, MD 20850.

7. Defendant David Kappos is sued in his official capacity as Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office ("PTO"). The Director of the PTO is designated by statute as the official responsible for determining the period of patent term adjustments, and thus is the proper defendant in a suit seeking review of such determinations. *See* 35 U.S.C. §§ 154(b)(3) and 154(b)(4)(A).

### **BACKGROUND**

8. Section 154 of title 35 of the United States Code requires that the Director of the PTO grant a patent term adjustment (“PTA”) in accordance with the provisions of section 154(b).

9. In determining patent term adjustment (“PTA”), the Defendant must take into account PTO delays under 35 U.S.C. § 154(b)(1), any overlap in PTO delays under 35 U.S.C. § 154(b)(2)(A), and any “Applicant delay” under 35 U.S.C. § 154(b)(2)(C).

10. PTO delays under 35 U.S.C. § 154(b)(1) break down into three categories known as “A delay,” “B delay,” and “C delay.” Only “A delay” and “B delay” are at issue in this case.

11. “A delay” occurs when the PTO fails to act within a particular time period; for example, if the PTO does not “issue a patent within four months after the date on which the issue fee was paid . . . and all other outstanding requirements were satisfied.” *See* 35 U.S.C. § 154(b)(1)(A). The statute provides that “the term of the patent shall be extended by 1 day for each day after the end of the period specified . . . until the action described . . . is taken.” *Id.*

12. “B delay” occurs when the PTO fails to issue a patent within three years of the actual filing date of the patent application, excluding certain periods of delay attributable to the applicant. *See* 35 U.S.C. § 154(b)(1)(B). Similarly to “A delays,” the statute provides that “[T]he term of the patent shall be extended by 1 day for each day after the end of that 3-year period until the patent is issued.” *Id.*

13. 35 U.S.C. § 154(b)(3)(B) states that “the Director shall- (i) make a determination of the period of any patent term adjustment under this subsection, and shall transmit a notice of that determination with the written notice of allowance of the application . . . .”

14. The PTO had taken the position that whenever an application is subject to both “A delay” and “B delay,” those periods always “overlap” within the meaning of 35 U.S.C. § 154(b)(2)(A) even if they occur on different calendar days. Thus, for the purposes of PTA, the PTO counted the greater of the “A delay” or the “B delay,” but never both periods of delay.

15. This Court rejected the PTO’s interpretation of 35 U.S.C. § 154(b)(2)(A) in *Wyeth v. Dudas*, 580 F. Supp. 2d 138 (D.D.C. 2008), and this holding was affirmed by the Federal Circuit in *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010). The Court held that “[t]he only way that periods of time can ‘overlap’ is if they occur on the same day” under 35 U.S.C. § 154(b)(2). *Id.* at 141. Thus, “[i]f an ‘A delay’ occurs on one calendar day and a ‘B delay’ occurs on another, they do not overlap, and § 154(b)(2)(A) does not limit the extension to one day.” *Id.* at 141-42.

16. “Applicant delay” under 35 U.S.C. § 154(b)(2)(C) arises where an applicant “failed to engage in reasonable efforts to conclude prosecution of the application,” and results in a reduction of any accumulated PTA. *See* 37 C.F.R. § 1.704(a). The Director has prescribed regulations setting out the specific circumstances deemed to be “Applicant delay.” *See* 37 C.F.R. § 1.704.

17. At issue here is “Applicant delay” arising under 37 C.F.R. §§ 1.704(b), 1.704(c)(7) and 1.704(c)(8). Under 37 C.F.R. § 1.704(b), failure to reply within three months to “any notice or action by the Office making any rejection, objection, argument, or other request,” results in a reduction of PTA “by the number of days, if any, beginning on the day after the date that is three months after the date of mailing or transmission of the office communication notifying the applicant of the rejection, objection, argument or other request and ending on the date the reply was filed.”

18. Under 37 C.F.R. § 1.704(c)(8), “[s]ubmission of a supplemental reply or other paper, other than a supplemental reply or other paper expressly requested by the examiner, after a reply has been filed” constitutes “Applicant delay.” delay under 37 C.F.R. § 1.704(c)(8) reduces PTA by “the number of days beginning on the day after the date the initial reply was filed and ending on the date that the supplemental reply or other such paper was filed.” Similarly, under 37 C.F.R. § 1.704(c)(7), “[s]ubmission of a reply having an omission ([37 C.F.R.] § 1.135(c))” constitutes “Applicant delay” and reduces PTA “by the number of days, if any, beginning on the day after the date the reply having an omission was filed and ending on the date that the reply or other paper correcting the omission was filed.”

19. Further at issue here is 37 C.F.R. 1.703(b) and 37 C.F.R. 1.703(b)(4), which state that the “period of adjustment under 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed . . . and ending in the date a patent was issued, but not including the sum of the following periods: . . . (4) The number of days, if any, in the period beginning on the date on which a notice of appeal to the Board of Appeals and Interferences was filed . . . and ending on the date of mailing of . . . a notice of allowance under 35 U.S.C. § 151.”

20. Under 35 U.S.C. § 154(b)(4)(A), “[a]n applicant dissatisfied with a determination made by the Director under paragraph (3) shall have remedy by a civil action against the Director filed in the United States District Court for the District of Columbia within 180 days after the grant of the patent. Chapter 7 of title 5 shall apply to such action.”

### **The '351 Patent**

21. Craig A. Rosen, Michael W. Laird, and Reiner L. Gentz are the inventors of the '351 patent, entitled “Antibodies Against Protective Antigen,” which issued from U.S. Patent

Application No. 10/602,727 (“the ’727 application”) on October 13, 2009. The ’351 patent is attached hereto as Exhibit A.

22. HGS is the assignee of the ’351 patent, as evidenced by the assignment documents recorded at the PTO.

23. The ’351 patent was filed on June 25, 2003, and is thus eligible for PTA under 35 U.S.C. § 154.

24. The ’351 patent is not subject to a terminal disclaimer.

25. The PTO failed to act on the ’727 application within 14 months of the actual filing date. Thus, Plaintiff is entitled to 559 days of “A delay” due to the PTO’s delay from the day after the date fourteen months after the application was filed (August 26, 2004) to the date of mailing of the first notification under 35 U.S.C. § 132 (March 7, 2006). *See* 35 U.S.C. § 154(b)(1)(A)(i) and 37 C.F.R. §§ 1.702(a)(1) & 1.703(a)(1).

26. A complete reply to the March 7, 2006 office action was filed on July 7, 2006 with a petition for an extension of time of three months. Pursuant to 37 C.F.R. § 1.704, this filing incurred a PTA reduction of 30 days from the day after the date three months after the mailing date of the office action (June 8, 2006) to the date of the response (July 7, 2006).

27. An information disclosure statement (“IDS”) was filed on July 11, 2006. According to the Defendant, PTA was reduced by 4 days as a result of this filing. *See* Exhibit C, Dismissal of Application for Patent Term Adjustment, at 2-3. This reduction in PTA is in error because the reply filed July 7, 2006 was a complete reply under 35 U.S.C. § 132 in compliance with 35 U.S.C. § 154(b)(1)(A)(ii) and 37 C.F.R. §§ 1.702(a)(2) and 1.703(a)(2) to the office action of March 7, 2006. Thus, the IDS was not a “supplemental reply or other paper” under 37 C.F.R. § 1.704(c)(8).

28. Additionally, the PTO did not provide the July 7, 2006 filing to the responsible patent examiner until July 11, 2006, the same day as the July 11, 2006 IDS was filed. Thus, the IDS filing could not have delayed the patent examiner's consideration of Plaintiff's reply or the preparation of a response under 35 U.S.C. § 132. Accordingly, the submission of the IDS on July 11, 2006 cannot constitute a failure to "engage in reasonable efforts to conclude prosecution."

29. A Notice to Comply requesting a new Sequence Listing was mailed on October 13, 2006. The Notice to Comply to the Sequence Listing was incorrectly treated as a proper response to Plaintiff's reply of July 7, 2006. *See* Exhibit C, Dismissal of Application for Patent Term Adjustment, at 3-4. According to the Defendant, the period of adjustment was erroneously calculated as a 64-day adjustment, instead of a 254-day adjustment for the reasons discussed below. A response to the Notice to Comply was filed on January 16, 2007 with a petition for extension of time of two months. Pursuant to 37 C.F.R. § 1.704, this filing incurred a PTA reduction of 3 days from the day after the date that was three months after the mailing of the notice (January 14, 2007) to the date of the response (January 16, 2007).

30. A non-final office action responsive to Plaintiff's July 7, 2006 reply was mailed on July 19, 2007. Accordingly, Plaintiff is entitled to 254 days of "A delay" due to the PTO's delay in responding from the day after the date that is four months after the reply was filed (November 8, 2006) and ending on the date of mailing of the non-final office action under 35 U.S.C. § 132 (July 19, 2007). *See* 37 C.F.R. §§ 1.702(a)(2) and 1.703(a)(2).

31. A response to the July 19, 2007 non-final office action was filed on January 22, 2008 with a petition for an extension of time of three months. Pursuant to 37 C.F.R. § 1.704, this

filing incurred a PTA reduction of 95 days from the day after the date that was three months after the mailing of the office action (October 20, 2007) to the date of the response (January 22, 2008).

32. A final office action was mailed on April 28, 2008. A response to the final office action was filed on October 27, 2008 with a petition for an extension of time of three months. Pursuant to 37 C.F.R. § 1.704, this filing incurred a PTA reduction of 91 days from the day after the date that was three months after the mailing of the office action (July 29, 2008) to the date of the response (October 27, 2008).

33. On December 10, 2008, a Notice of Allowance was mailed together with a determination of patent term adjustment of 400 days.

34. The issue fee transmittal form was filed and the issue fee was timely paid on March 6, 2009.

35. An Application for Patent Term Adjustment under 37 C.F.R. § 1.705(b) was timely filed on March 6, 2009. On September 14, 2009, Defendant mailed a decision indicating that the Application for Patent Term Adjustment was dismissed.

36. The Defendant, in its dismissal of Plaintiff's Application for Patent Term Adjustment stated that Plaintiff's July 7, 2006 reply to the office action constituted a reply having an omission under 37 C.F.R. § 1.704(c)(7). *See* Exhibit C, at 3. Plaintiff believes this determination to be incorrect. *Id.* at 4. Furthermore, Defendant stated that the IDS filed on July 11, 2006 constituted "Applicant delay" under 37 C.F.R. § 1.704(c)(8). *Id.* at 2-3. Plaintiff believes this determination is also incorrect; however, in the event this Court agrees with Defendant, Plaintiff would incur an additional reduction of PTA of 4 days from the date the Plaintiff filed its reply (July 7, 2006) until the date the IDS was filed (July 11, 2006).



37. The '351 patent issued on October 13, 2009; thus, the PTO failed to issue the '351 patent within four months of the payment of the issue fee pursuant to 35 U.S.C. § 154(b)(1)(A)(iv). Thus, Plaintiff is entitled to 99 days of "A delay" due to the PTO's delay from the day after the date four months after the issue fee was paid (March 7, 2009) to the date of issuance of the '351 patent (October 13, 2009). *See* 35 U.S.C. § 154(b)(1)(A)(iv) and 37 C.F.R. §§ 1.702(a)(4) & 1.703(a)(6).

38. Furthermore, the PTO failed to issue the '351 patent within three years of its actual filing date pursuant to 35 U.S.C. § 154(b)(1)(B). Thus, Plaintiff is entitled to 1,206 days of "B delay" due to the PTO's failure to issue the patent from the day after the date that was three years after the application was filed (June 26, 2006) to the date that the patent was issued (October 13, 2009). *See* 35 U.S.C. § 154(b)(1)(B) and 37 C.F.R. § 1.703(b).

39. Accordingly, "A delay" under 35 U.S.C. § 154(b)(1)(A) amounted to 912 days (559 days + 254 days + 99 days). "B delay" under 35 U.S.C. § 154(b)(1)(B) amounted to 1,206 days. There were 353 days of overlap between the "A delay" and "B delay." Thus total PTO delay amounted to 1,765 days (559 days + 1,206 days). Total "Applicant delay" amounted to 219 days. Thus, the total correct PTA for the '351 patent is 1,546 days.

40. On November 13, 2009, Plaintiff timely filed a Request for Reconsideration of Decision on Application for Patent Term Adjustment Under 37 C.F.R. § 1.705(b) and Application for Patent Term Adjustment Under 37 C.F.R. § 1.705(d). The request demonstrated that the correct PTA for the '351 patent is 1,546 days, rather than 983 days as stated on the face of the patent.

41. On April 12, 2010, the Defendant issued a decision on Plaintiff's Request for Reconsideration of Patent Term Adjustment, granting Plaintiff's request in part. *See* Exhibit E.

In its decision, Defendant stated that the period of overall adjustment to which the patent is entitled is 1,497 days. Defendant calculated that the "A delay" amounted to 722 days (559 days + 64 days + 99 days), the "B delay" amounted to 1,206 days, and that there were 163 days of overlap between the "A delay" and "B delay." Defendant determined that the total period of applicant delay was 223 days and that there was a further reduction of patent term adjustment of 45 days pursuant to 37 C.F.R. 1.703(b)(4) in connection with the Notice of Appeal filed October 27, 2008.

42. In its decision, Defendant determined that Plaintiff is entitled to an overall adjustment of 1,497 days (722 days of "A delay," plus 1206 days of "B delay," minus 163 overlapping days, 45 days pursuant to 37 C.F.R. § 1.703(b)(4), and 223 days of applicant delay). Defendant disagreed that the total "A delay" was 912 days and that applicant delay amounted to 219 days. Defendant also determined that a reduction of patent term adjustment of 45 days pursuant to 37 C.F.R. 1.703(b)(4) should be subtracted from the total PTO delay.

43. The PTO's decision on Plaintiff's Request for Reconsideration of Patent Term Adjustment for the '351 patent was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A). On May 12, 2010, Plaintiff timely filed a Request for Reconsideration of Decision Regarding Patent Term Adjustment, requesting that Defendant reconsider its April 12, 2010 decision to reduce Plaintiff's patent term adjustment by 45 days and award at least 1,542 days rather than 1,497 days. Defendant has not issued a decision on Plaintiff's request.

#### **The '236 Patent**

44. Steven M. Ruben, Steven C. Barash, Gil H. Choi, Tristan Vaughan, and David Hilbert are the inventors of the '236 patent, entitled "Antibodies that Immunospecifically Bind to

B Lymphocyte Stimulator Protein,” which issued from U.S. Patent Application No. 11/266,444 (“the ’444 application”) on October 20, 2009. The ’236 patent is attached hereto as Exhibit B.

45. HGS is the assignee of the ’236 patent, as evidenced by the assignment documents recorded in the PTO.

46. The ’236 patent was filed on November 4, 2005, and is thus eligible for PTA under 35 U.S.C. § 154.

47. The ’236 patent is not subject to a terminal disclaimer.

48. The PTO failed to act on the ’444 application within 14 months of the actual filing date. Plaintiff is thus entitled to “A delay” of 110 days due to the PTO’s delay from the day after the date fourteen months after the application was filed (January 5, 2007) to the date of mailing of the first notification under 35 U.S.C. § 132 (April 24, 2007). *See* 35 U.S.C. § 154(b)(1)(A)(i) and 37 C.F.R. §§ 1.702(a)(1) and 1.703(a)(1).

49. A complete reply to the April 24, 2007 office action was filed on July 23, 2007 with a petition for an extension of time of two months. The complete reply was filed within three months after the mailing of the office action (April 24, 2007), thereby incurring no reduction in PTA under 37 C.F.R. § 1.704.

50. An IDS was filed on September 10, 2007. According to the Defendant, PTA was reduced by 49 days as a result of this filing. *See* Exhibit D, Dismissal of Application for Patent Term Adjustment, at 1-2. Pursuant to 37 C.F.R. § 1.97(b)(3), an IDS filed before the mailing of a first Office Action on the merits shall be considered by the Office. Thus, this reduction in PTA is in error because the filing of the IDS prior to the first office action in accordance with PTO rules does not constitute a failure of Applicants to engage in reasonable efforts to conclude examination of the application under 37 C.F.R. § 1.704(c).

51. A non-final office action was mailed on February 28, 2008. However, the PTO failed to respond under 35 U.S.C. § 154(b)(1)(A)(ii) within the four month permitted time frame after Plaintiff's July 23, 2007 reply. Accordingly, Plaintiff is entitled to "A delay" of 97 days due to the PTO's delay from the day after the date four months after the reply was filed (November 24, 2007) until the date of mailing of the non-final office action under 35 U.S.C. § 132 (February 28, 2008). *See* 37 C.F.R. §§ 1.702(a)(2) & 1.703(a)(2).

52. A response to the February 28, 2008 non-final office action was filed on June 30, 2008 with a petition for an extension of time of one month. Pursuant to 37 C.F.R. § 1.704, this filing incurred a PTA reduction of 33 days from the day after the date three months after the mailing of the office action (May 29, 2008) to the date of the response (June 30, 2008).

53. A notice of informal or non-responsive amendment was mailed on August 4, 2008. A response to the August 4, 2008 notice of informal or non-responsive amendment was filed on August 15, 2008. Pursuant to 37 C.F.R. § 1.704, this filing incurred a PTA reduction of 46 days from the day after the date three months after the mailing of the office action (May 29, 2008) to the date of the response (August 15, 2008).

54. An IDS was filed on August 28, 2008. According to the Defendant, PTA was reduced by 13 days as a result of this filing. *See* Exhibit D, Dismissal of Application for Patent Term Adjustment, at 3. However, this reduction in PTA is in error because the reply filed August 15, 2008 was a complete reply under 35 U.S.C. § 132 in compliance with 35 U.S.C. § 154(b)(1)(A)(ii) and 37 C.F.R. §§ 1.702(a)(2) and 1.703(a)(2) to the office action of February 28, 2008. Thus, the IDS was not a "supplemental reply or other paper" under 37 C.F.R. § 1.704(c)(8).

55. Additionally, the PTO did not forward Plaintiff's August 15, 2008 filing to the responsible patent examiner until September 19, 2008, more than one month after the August 28, 2008 IDS was filed. Thus, the IDS filing could not have delayed the patent examiner's consideration of Plaintiff's filing or the preparation of a response under 35 U.S.C. § 132, and thus the submission of the IDS on August 28, 2008 cannot constitute a failure to "engage in reasonable efforts to conclude prosecution."

56. On April 2, 2009, a Notice of Allowance was mailed together with a Determination of Patent Term Adjustment under 35 U.S.C. § 154 indicating a PTA of 66 days.

57. The issue fee transmittal form was filed and the issue fee was timely paid, on July 2, 2009.

58. An Application for Patent Term Adjustment was timely filed on July 2, 2009. On September 16, 2009, the PTO mailed a decision indicating that the Application for Patent Term Adjustment was dismissed.

59. The '236 patent issued on October 20, 2009. Thus, the PTO failed to issue the patent within three years pursuant to 35 U.S.C. § 154(b)(1)(B). As a result, Plaintiff is entitled to 350 days of "B delay" due to the PTO's delay in issuing the patent from the day after the date that was three years after the application was filed (November 5, 2008) to the date that the patent was issued (October 20, 2009). *See* 35 U.S.C. § 154(b)(1)(B) and 37 C.F.R. § 1.703(b).

60. In sum, "A delay" under 35 U.S.C. § 154(b)(1)(A) amounted to 207 days. "B delay" under 35 U.S.C. § 154(b)(1)(B) amounted to 350 days. There were 0 days of overlap between the "A delay" and the "B delay." Thus, total PTO delay amounted to 557 days (350 days + 207 days). Total Applicant delay amounted to 79 days or, if the Defendant's

determination is accepted, at least no more than 141 days. Thus, the total PTA for the '236 patent is 478 days, or at least 416 days if the Defendant's determination is accepted.

61. On November 16, 2009, Plaintiff filed a timely Request for Reconsideration of Decision on Application for Patent Term Adjustment Under 37 C.F.R. § 1.705(b) and Application for Patent Term Adjustment Under 37 C.F.R. § 1.705(d). The request demonstrated that the correct PTA for the '236 patent is 478 days, or at least 416 days, rather than 209 days as currently calculated. The PTO has not yet issued a decision on this petition.

62. The PTO's determination of the patent term adjustment for the '351 patent was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A).

#### **The '189 Patent**

63. Theodora Salcedo, Steven M. Ruben, Craig A. Rosen, Vivian R. Albert, Claire Dobson, and Tristan Vaughan are the inventors of the '189 patent, entitled "Antibodies that Immunospecifically Bind to TRAIL Receptors," which issued from U.S. Patent Application No. 10/139,785 ("the '785 application") on June 20, 2006. The '189 patent is attached hereto as Exhibit F.

64. HGS is the assignee of the '189 patent, as evidenced by the assignment documents recorded in the PTO.

65. The '189 patent was filed on May 7, 2002, and is thus eligible for PTA under 35 U.S.C. § 154.

66. The '189 patent is not subject to a terminal disclaimer.

67. The PTO failed to act on the '785 application within 14 months of the actual filing date. Plaintiff is thus entitled to "A delay" of 128 days due to the PTO's delay from the

day after the date fourteen months after the application was filed (July 8, 2003) to the date of mailing of the first notification under 35 U.S.C. § 132 (November 12, 2003). *See* 35 U.S.C. § 154(b)(1)(A)(i) and 37 C.F.R. §§ 1.702(a)(1) and 1.703(a)(1).

68. The PTO failed to issue the '189 patent within four months of payment of the issue fee. Accordingly, Plaintiff is entitled to "A delay" of 198 days from the day after four months from paying the issue fee (December 5, 2005) to the issuance of the '189 patent (June 20, 2006). *See* 37 C.F.R. 1.703(a)(6).

69. Thus, the total "A delay" amounts to 326 days.

70. The '189 patent issued on June 20, 2006. Thus, the PTO failed to issue the patent within three years pursuant to 35 U.S.C. § 154(b)(1)(B). As a result, Plaintiff is entitled to 409 days of "B delay" due to the PTO's delay in issuing the patent from the day after the date that was three years after the application was filed (May 8, 2005) to the date that the patent was issued (June 20, 2006). *See* 35 U.S.C. § 154(b)(1)(B) and 37 C.F.R. § 1.703(b).

71. The total of the PTO "A delay" and "B delay" amounts to 735 days (i.e., 326 days + 409 days). However, some of the "A delays" occurred after the "B delay" began on May 8, 2005, i.e., some of the "A delay" overlaps with the "B delay" in the time period after May 7, 2005. *See* 37 C.F.R. § 1.703(f).

72. In particular, the first "A delay" discussed above (i.e., 128 days) does not overlap with the "B delay" period. The remaining "A delay" overlaps with the "B delay," specifically, the second "A delay" discussed above (i.e., 198 days). Thus, there were 198 days of overlap of "A and B delays."

73. Accordingly, the total PTO delay amounts to 537 days (i.e., 735 days minus 198 days).

74. Applicant delay amounts to 138 days (37 C.F.R. § 1.704(a)) based on the following periods of delay: (a) a delay of 82 days for submission of a reply to an Office Action on August 31, 2004 more than 3 months after the Office Action had been mailed on March 10, 2004 (37 C.F.R. § 1.704(b)), (b) a delay of 28 days for submission of a reply to an Office Action on March 18, 2005 more than 3 months after the Office Action had been mailed on November 18, 2004 (37 C.F.R. § 1.704(b)), and (c) a delay of 28 days for the submission of a supplemental response on April 15, 2005, after a response had been filed on March 18, 2005 (37 C.F.R. § 1.704(c)(8)).

75. In sum, “A delay” under 35 U.S.C. § 154(b)(1)(A) amounted to 326 days. “B delay” under 35 U.S.C. § 154(b)(1)(B) amounted to 409 days. There were 198 days of overlap between the “A delay” and the “B delay.” Thus, total PTO delay amounted to 537 days (326 days + 409 days – 198 days). Total Applicant delay amounted to 138 days. Thus, the total PTA for the ’189 patent is 399 days (735 days – 138 days).

76. The ’189 patent issued on June 20, 2006 and states on its face that it is subject to 271 days of patent term adjustment.

77. On March 5, 2010, Plaintiff filed a Petition to Invoke the Supervisory Authority of the Director (37 C.F.R. § 1.181(a)(3)) and/or Petition to Suspend 37 C.F.R. § 1.705(d) (37 C.F.R. § 1.183). The petition demonstrated that the correct PTA for the ’189 patent is 399 days rather than 271 days as currently calculated. The PTO dismissed this petition on April 21, 2010. See Exhibit G.

78. The PTO’s determination of the patent term adjustment for the ’351 patent was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A).



**The '501 patent**

79. Steven M. Ruben, Gil H. Choi, Tristan Vaughan, and David Hilbert are the inventors of the '501 patent, entitled "Antibodies that Immunospecifically Bind BLYS," which issued from U.S. Patent Application No. 09/880,748 ("the '748' application") on November 21, 2006. The '501 patent is attached hereto as Exhibit H.

80. HGS is the assignee of the '501 patent, as evidenced by the assignment documents recorded in the PTO.

81. The '501 patent was filed on June 15, 2001, and is thus eligible for PTA under 35 U.S.C. § 154.

82. The '501 patent is not subject to a terminal disclaimer.

83. The PTO failed to act on the '748 application within 14 months of the actual filing date. Plaintiff is thus entitled to "A delay" of 265 days due to the PTO's delay from the day after the date fourteen months after the application was filed (August 16, 2002) to the date of mailing of the first notification under 35 U.S.C. § 132 (May 7, 2003). *See* 35 U.S.C. § 154(b)(1)(A)(i) and 37 C.F.R. §§ 1.702(a)(1) and 1.703(a)(1).

84. The second "A delay" occurred from the day after four months from filing a response to the restriction requirement (i.e., November 8, 2003) to the mailing of the first office action (i.e., until September 14, 2004). The second "A delay" totals 312 days.

85. The third "A delay" occurred from the day after four months from filing a response to the first office action (i.e., from April 15, 2005) to the mailing of the final office action (i.e., until May 4, 2005). The third "A delay" totals 20 days.

86. The fourth "A delay" occurred from the day after four months after filing a response to the final office action (i.e., from December 5, 2005) to the mailing of a notice of allowance (i.e., until December 21, 2005). The fourth "A delay" totals 17 days.

87. The fifth "A delay" occurred from the day after four months from paying the issue fee (i.e., from July 21, 2006) to the issuance of the '501 patent (i.e., until November 21, 2006). The fifth delay totals 124 days.

88. Thus, the total "A delay" amounts to 738 days.

89. On December 21, 2005, a Notice of Allowance was mailed together with a Determination of Patent Term Adjustment under 35 U.S.C. § 154 indicating a PTA of 354 days.

90. The issue fee transmittal form was filed and the issue fee was timely paid, on March 20, 2006.

91. An Application for Patent Term Adjustment (*See* Exhibit I) was timely filed on March 20, 2006. On June 12, 2006, the PTO mailed a decision indicating that the Application for Patent Term Adjustment was granted (*See* Exhibit J).

92. The Issue Notification for the '501 patent states that the patent term adjustment is 754 days. *See* Exhibit K.

93. The '501 patent issued on October 20, 2009. Thus, the PTO failed to issue the patent within three years pursuant to 35 U.S.C. § 154(b)(1)(B). As a result, Plaintiff is entitled to 889 days of "B delay" due to the PTO's delay in issuing the patent from the day after the date that was three years after the application was filed (June 16, 2004) to the date that the patent was issued (November 21, 2006). *See* 35 U.S.C. § 154(b)(1)(B) and 37 C.F.R. § 1.703(b).

94. Total PTO delay amounts to 1627 days (i.e., 738 days + 889 days). However, some of the "A delay" occurred after the "B delay" began on June 16, 2004, i.e., some of the "A

delay” overlaps with the “B delay” in the time period after June 15, 2004. *See* 37 C.F.R. § 1.703(f). In particular, the first “A delay” discussed above (i.e., 265 days) and the portion of the second “A delay” discussed above up until the beginning of the “B delay” after June 15, 2004 (i.e., 221 days) do not overlap with the “B delay” period. The remaining “A delay”s overlap with the “B delay” period, including the portion of the second “A delay” discussed above after June 15, 2004 (i.e., 91 days), the third “A delay” (i.e., 20 days), the fourth “A delay” (i.e., 17 days), and the fifth “A delay” (i.e., 124 days). Thus, there were 252 days of overlap of “A and B delays”. Accordingly, the total PTO delay amounts to 1,375 days (i.e., 1,627 days minus 252 days).

95. Applicant delay amounts to 240 days (37 C.F.R. § 1.704(a)) based on the following periods of delay: (a) a delay of 151 days from the filing of a reply to an office action on July 7, 2003, to the submission of an information disclosure statement on December 5, 2003 (37 C.F.R. § 1.704(c)(8)), (b) a delay of 35 days from the filing of a reply to an office action on December 14, 2004, to the submission of a clean copy of the substitute specification on January 18, 2005 ((37 C.F.R. § 1.704(b)), and (c) a delay of 54 days from the filing of an after-final reply on August 5, 2005, to the submission of a supplemental after-final reply on September 27, 2005 (37 C.F.R. § 1.704(b)). *See* Exhibits I and J respectively, Petition for Patent Term Adjustment and Decision Granting Petition for Patent Term Adjustment.

96. In sum, “A delay” under 35 U.S.C. § 154(b)(1)(A) amounted to 738 days. “B delay” under 35 U.S.C. § 154(b)(1)(B) amounted to 738 days. There were 252 days of overlap between the “A delay” and the “B delay.” Thus, total PTO delay amounted to 1,375 days (738 days + 889 days - 252 days). Total Applicant delay amounted to 240 days. Thus, the total PTA for the ’501 patent is 1,135 days.

97. On March 5, 2010, Plaintiff filed a Petition to Invoke the Supervisory Authority of the Director (37 C.F.R. § 1.181(a)(3)) and/or Petition to Suspend 37 C.F.R. § 1.705(d) (37 C.F.R. § 1.183). The petition demonstrated that the correct PTA for the '501 patent is 1,135 days, rather than 754 days as currently calculated. The PTO has not yet issued a decision on this petition.

98. The PTO's determination of the patent term adjustment for the '501 patent was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A).

**CLAIM FOR RELIEF**

**COUNT ONE**

**(Patent Term Adjustment Under 35 U.S.C. § 154(b)(4)(A))**

99. The allegations of paragraphs 1-98 are incorporated in this claim for relief as if fully set forth herein.

**The '351 patent**

100. The patent term adjustment for the '351 patent, as determined by the Defendant in its Decision on Request for Reconsideration of Patent Term Adjustment under 35 U.S.C. § 154(b) and as stated on the Certificate of Correction is 1,497 days. *See* Exhibit E at 2 and 4.

101. Under 35 U.S.C. § 154(b)(1)(A), Plaintiff is entitled to an adjustment of the term of the '351 patent of 912 days, the number of days attributable to PTO examination delay ("A delay").

102. Under 35 U.S.C. § 154(b)(1)(B), Plaintiff is entitled to an additional adjustment of the term of the '351 patent of a period of 1,206 days, which is the number of days the issue date of the '351 patent exceeded three years (from June 26, 2006 until October 13, 2009) ("B delay").

103. 35 U.S.C. § 154(b)(2)(A) provides that "to the extent that periods of delay attributable to grounds specified in paragraph [b](1) overlap, the period of any adjustment . . . shall not exceed the actual number of days the issuance of the patent was delayed." In *Wyeth v. Dudas*, 580 F. Supp. 2d 138 (D.D.C. 2008), this Court explained that for purposes of identifying "overlap" between "A delay" and "B delay" under 35 U.S.C. § 154(b)(2)(A), the "period of delay" for "B delay" begins when the PTO has failed to issue a patent within three years, not before.

104. In accordance with *Wyeth*, the correct patent term adjustment under 35 U.S.C. § 154(b)(1) and (2) is the sum of the “A delay” and “B delay” (912 days + 1,206 days = 2,118 days) reduced by the number of days of “A delay” that overlaps with “B delay” (353 days) and reduced by the number of days of applicant delay (219 days) for a net adjustment of 1,546 days.

105. The Director erred in the determination of patent term adjustment by treating the filing of an IDS as a supplemental reply or other paper under 37 C.F.R. § 1.704(c)(8), and in holding that the filing of the IDS constituted a failure to engage in reasonable efforts to conclude prosecution under the circumstances. Thus, the Director erroneously determined that the Applicant delay amounted to 223 days, rather than the correct number of 219 days.

106. The Director erred in the determination of patent term adjustment by treating the notice to comply requesting a new sequence listing as a proper response to Plaintiff’s reply of July 7, 2006. Thus, the Director erroneously determined that the PTO “A delay” was 722 days and not 912 days.

107. The Director erred in the determination of patent term adjustment by reducing the PTO delay by the number of days from the date of filing a Notice of Appeal to the date the notice of allowance was mailed under 37 C.F.R. 1.703(b)(4). Thus, the Director erroneously determined that the PTO delay amounted to 1720 days, rather than 1765 days.

108. The Director’s determination that the ‘351 patent is entitled to only 1,497 days of patent term adjustment is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law and in excess of statutory jurisdiction, authority, or limitation.

**The '236 patent**

109. The patent term adjustment for the '236 patent, as determined by the Defendant under 35 U.S.C. § 154(b) and listed on the face of the '236 patent, is 209 days. See Exhibit B at 1.

110. Under 35 U.S.C. § 154(b)(1)(A), Plaintiff is entitled to an adjustment of the term of the '236 patent of 207 days, the number of days attributable to PTO examination delay ("A delay") as calculated by the PTO.

111. Under 35 U.S.C. § 154(b)(1)(B), Plaintiff is entitled to an additional adjustment of the term of the '236 patent of a period of 350 days, which is the number of days the issue date of the '236 patent exceeded three years (from November 5, 2008 until October 20, 2009) ("B delay").

112. 35 U.S.C. § 154(b)(2)(A) provides that "to the extent that periods of delay attributable to grounds specified in paragraph [b](1) overlap, the period of any adjustment . . . shall not exceed the actual number of days the issuance of the patent was delayed." In *Wyeth v. Dudas*, 580 F. Supp. 2d 138, 141 (D.D.C. 2008) this Court explained that for purposes of identifying "overlap" between "A delay" and "B delay" under 35 U.S.C. § 154(b)(2)(A), the "period of delay" for "B delay" begins when the PTO has failed to issue a patent within three years, not before.

113. In accordance with *Wyeth*, the correct patent term adjustment under 35 U.S.C. § 154(b)(1) and (2) is the sum of the "A delay" and "B delay" (557 days) reduced by the number of days of "A delay" that overlaps with "B delay" (0 days) and reduced by the number of days of Applicant delay (79 days, or at least not more than 141 days) for a net adjustment of 478 days, or at least not less than 416 days.

114. The Director erred in the determination of patent term adjustment by treating the filing of two IDS submissions as “Applicant delay” under 37 C.F.R. § 1.704(c)(8), and in holding that the filing of the IDS submissions constituted failures to engage in reasonable efforts to conclude prosecution under the circumstances. Thus, the Director erroneously determined that the Applicant delay amounted to 141 days, rather than the correct number of 79 days.

115. The Director erred in the determination of patent term adjustment by treating the “period of delay” for “B delay” for purposes of identifying “overlap” under 35 U.S.C. § 154(b)(2)(A), as running from the filing date of the patent application rather than beginning when the PTO has failed to issue a patent within three years. Thus, the Director erroneously determined that all of the “A delay” overlapped with the “B delay” under 35 U.S.C. § 154(b)(2)(A), whereas the “A delay” and “B delay” did not overlap on any calendar day.

116. The Director’s determination that the ’236 patent is entitled to only 209 days of patent term adjustment is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law and in excess of statutory jurisdiction, authority, or limitation.

## **COUNT TWO**

### **(Patent Term Adjustment Under 35 U.S.C. § 154)**

117. The allegations of paragraphs 1-116 are incorporated in this claim for relief as if fully set forth herein.

#### **The ’189 patent**

118. The patent term adjustment for the ’189 patent, as determined by the Defendant under 35 U.S.C. § 154(b) and listed on the face of the ’189 patent, is 271 days. See Exhibit F at 1.



119. Under 35 U.S.C. § 154(b)(1)(A), Plaintiff is entitled to an adjustment of the term of the '189 patent of 326 days, the number of days attributable to PTO examination delay ("A delay") as calculated by the PTO.

120. Under 35 U.S.C. § 154(b)(1)(B), Plaintiff is entitled to an additional adjustment of the term of the '189 patent of a period of 409 days, which is the number of days the issue date of the '189 patent exceeded three years (from May 8, 2005 until June 20, 2006) ("B delay").

121. 35 U.S.C. § 154(b)(2)(A) provides that "to the extent that periods of delay attributable to grounds specified in paragraph [b](1) overlap, the period of any adjustment . . . shall not exceed the actual number of days the issuance of the patent was delayed." In *Wyeth v. Dudas*, 580 F. Supp. 2d 138, 141 (D.D.C. 2008) this Court explained that for purposes of identifying "overlap" between "A delay" and "B delay" under 35 U.S.C. § 154(b)(2)(A), the "period of delay" for "B delay" begins when the PTO has failed to issue a patent within three years, not before.

122. In accordance with *Wyeth*, the correct patent term adjustment under 35 U.S.C. § 154(b)(1) and (2) is the sum of the "A delay" and "B delay" (735 days) reduced by the number of days of "A delay" that overlaps with "B delay" (198 days) and reduced by the number of days of Applicant delay (138 days) for a net adjustment of 399 days.

123. The Director erred in the determination of patent term adjustment by treating the "period of delay" for "B delay" for purposes of identifying "overlap" under 35 U.S.C. § 154(b)(2)(A), as running from the filing date of the patent application rather than beginning when the PTO has failed to issue a patent within three years. Thus, the Director erroneously determined that all of the "A delay" overlapped with the "B delay" under 35 U.S.C. § 154(b)(2)(A), whereas the "A delay" and "B delay" did not overlap on any calendar day.

124. The Director's determination that the '189 patent is entitled to only 271 days of patent term adjustment is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law and in excess of statutory jurisdiction, authority, or limitation.

**The '501 patent**

125. The patent term adjustment for the '501 patent, as determined by the Defendant under 35 U.S.C. § 154(b) and listed on the face of the '501 patent, is 754 days. *See* Exhibit H at 1.

126. Under 35 U.S.C. § 154(b)(1)(A), Plaintiff is entitled to an adjustment of the term of the '501 patent of 738 days, the number of days attributable to PTO examination delay ("A delay") as calculated by the PTO.

127. Under 35 U.S.C. § 154(b)(1)(B), Plaintiff is entitled to an additional adjustment of the term of the '501 patent of a period of 889 days, which is the number of days the issue date of the '189 patent exceeded three years (from June 16, 2004 until November 21, 2006) ("B delay").

128. 35 U.S.C. § 154(b)(2)(A) provides that "to the extent that periods of delay attributable to grounds specified in paragraph [b](1) overlap, the period of any adjustment . . . shall not exceed the actual number of days the issuance of the patent was delayed." In *Wyeth v. Dudas*, 580 F. Supp. 2d 138, 141 (D.D.C. 2008) this Court explained that for purposes of identifying "overlap" between "A delay" and "B delay" under 35 U.S.C. § 154(b)(2)(A), the "period of delay" for "B delay" begins when the PTO has failed to issue a patent within three years, not before.

129. In accordance with *Wyeth*, the correct patent term adjustment under 35 U.S.C. § 154(b)(1) and (2) is the sum of the "A delay" and "B delay" (1627 days) reduced by the

number of days of "A delay" that overlaps with "B delay" (252 days) and reduced by the number of days of Applicant delay (240 days) for a net adjustment of 1135 days.

130. The Director erred in the determination of patent term adjustment by treating the "period of delay" for "B delay" for purposes of identifying "overlap" under 35 U.S.C. § 154(b)(2)(A), as running from the filing date of the patent application rather than beginning when the PTO has failed to issue a patent within three years. Thus, the Director erroneously determined that all of the "A delay" overlapped with the "B delay" under 35 U.S.C. § 154(b)(2)(A), whereas the "A delay" and "B delay" did not overlap on any calendar day.

131. The Director's determination that the '501 patent is entitled to only 754 days of patent term adjustment is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law and in excess of statutory jurisdiction, authority, or limitation.

**Inapplicability of Statutory Limitation**

132. The 180 day limitation period set forth in 35 U.S.C. § 154(b)(4)(A) applies to a re-determination of PTA by Defendant under "paragraph (3)," i.e., 35 U.S.C. § 154(b)(3).

133. 35 U.S.C. § 154(b)(3), by its plain terms, governs a PTA determination by Defendant only in conjunction with a notice of allowance of a patent application.

134. 35 U.S.C. § 154(b)(3) does not cover a PTA determination by Defendant in conjunction with the issuance of a patent.

135. Due to the narrow scope of 35 U.S.C. § 154(b)(3), the limitation period in 35 U.S.C. § 154(b)(4)(A) does not restrict the time within which a patentee, through a civil action in this District, may appeal a PTA determination by Defendant made contemporaneous with the grant of a patent.

136. In this action, HGS is seeking a recalculation of PTA for the '236, '351, '189, and '501 patents ("the HGS Patents") determined by Defendant upon issuance of each of these patents.

137. The 180 day limitation period set forth in 35 U.S.C. § 154(b)(4)(A) is inapplicable to HGS' claims herein. The 180 day limitation period set forth in 35 U.S.C. § 154(b)(4)(A) is inapplicable to HGS' claim herein. Nevertheless, this action was filed within 180 days of the issuance of the '236 and '351 patents.

138. HGS is not time barred by 35 U.S.C. § 154(b)(4)(A) in appealing the PTA determination by Defendant as to each of the HGS Patents.

139. HGS is entitled to additional patent term consistent with 35 U.S.C. § 154 and the *Wyeth* decision for each of the HGS Patents as reflected in paragraphs 1-138.

### **COUNT THREE**

#### **(Equitable Tolling)**

140. The allegations of paragraphs 1-139 are incorporated in this claim for relief as if fully set forth herein.

141. Even if the 180 day limitation period set forth in 35 U.S.C. § 154(b)(4)(A) is applicable to HGS' claim herein, it is a non-jurisdictional statute of limitations.

142. The equitable tolling doctrine is a creation of common law that has been read into every statute of limitations.

143. HGS lacked knowledge and adequate notice of its claim that Defendant had been improperly interpreting 35 U.S.C. § 154(b)(2)(A) in calculating the overlap of "A delay" and "B delay" and, thus, the appropriate patent term of each of the HGS' Patents until Defendant's announcement on January 21, 2010 that the PTO would not appeal the *Wyeth* decision.

144. HGS justifiably relied to its detriment upon Defendant's consistent and long standing, yet flawed, interpretation of 35 U.S.C. § 154(b)(2)(A) in calculating the overlap of "A delay" and "B delay" to determine PTA in failing to raise such a claim as to the '189 and '501 patents prior to Defendant's concession that the PTO would abide by the *Wyeth* decision.

145. Accordingly, the 180 day limitation period set forth in 35 U.S.C. § 154(b)(4)(A) should be equitably tolled from January 21, 2010.

146. HGS is entitled to additional patent term consistent with with 35 U.S.C. § 154 and *Wyeth* for each of the HGS Patents.

#### **COUNT FOUR**

##### **(Discovery Rule)**

147. The allegations of paragraphs 1-146 are incorporated in this claim for relief as if fully set forth herein.

148. The discovery rule, which governs a claim's accrual date for statute of limitations purposes, is distinct from equitable tolling.

149. Indeed, the discovery rule is to be applied in all federal question cases in the absence of a contrary directive from Congress.

150. The deprivation of patent term for each of the HGS Patents resulting from Defendant's failure to properly determine the overlap of "A delay" and "B delay" under 35 U.S.C. § 154(b)(2)(A) was not the sort of injury that could readily have been discovered by HGS at the time of the deprivation due to Defendant's consistent policy and practice of incorrectly interpreting and implementing this statutory provision by granting PTA amounting to the greater of "A delay" or "B delay."

151. HGS discovered, and with due diligence should have discovered, the deprivation of patent term for the '189 and '501 patents resulting from Defendant's failure to properly determine the overlap of "A delay" and "B delay" under 35 U.S.C. § 154(b)(2)(A) only when Defendant announced that the PTO would not appeal the *Wyeth* decision.

152. Accordingly, the 180 day limitation period set forth in 35 U.S.C. § 154(b)(4)(A) commenced on January 21, 2010.

153. HGS is entitled to additional patent term consistent with with 35 U.S.C. § 154 and *Wyeth* for each of the HGS Patents.

#### **COUNT FIVE**

##### **(Violation of the Fifth Amendment of the Constitution of the United States)**

154. The allegations of paragraphs 1-153 are incorporated in this claim for relief as if fully set forth herein.

155. The Fifth Amendment of the Constitution of the United States provides in relevant part, "[N]or shall private property be taken for public use, without just compensation."

156. HGS enjoys a substantial and cognizable private property right in the full and complete term of each of the HGS Patents.

157. HGS has paid all necessary maintenance fees to the PTO required to maintain its rights in each of the HGS Patents.

158. In calculating overlap of "A delay" and "B delay" pursuant to 35 U.S.C. § 154(b)(2)(A) when determining PTA for each of the HGS Patents, Defendant granted PTA amounting to the greater of "A delay" or "B delay."

159. Defendant's improper calculation of overlap of "A delay" and "B delay" when determining PTA for each of the HGS Patents permanently deprived HGS of patent term for

each of the HGS Patents to which it was entitled under 35 U.S.C. § 154(b) as reflected in the *Wyeth* decision.

160. Defendant's purposeful and deliberate diminution of the patent term of each of the HGS Patents constitutes a taking of HGS' property without just compensation, in violation of the Fifth Amendment of the Constitution of the United States.

### **COUNT SIX**

#### **(Declaratory Judgment Under the Administrative Procedures Act, 5 U.S.C. § 702 et seq.)**

161. The allegations of paragraphs 1-160 are incorporated in this claim for relief as if fully set forth herein.

162. In calculating overlap of "A delay" and "B delay" pursuant to 35 U.S.C. § 154(b)(2)(A) when determining PTA for each of the HGS Patents, Defendant granted PTA amounting to the greater of "A delay" or "B delay."

163. Defendant's improper calculation of overlap of "A delay" and "B delay" when determining PTA for each of the HGS Patents was contrary to law as evidenced by the *Wyeth* decision.

164. Defendant's determination of PTA for each of the HGS Patents was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law within the meaning of 5 U.S.C. § 706(2)(A); contrary to HGS' constitutional rights within the meaning of 5 U.S.C. § 706(2)(B); and in excess of statutory authority within the meaning of 5 U.S.C. § 706(2)(C).

165. Defendant's determination of PTA for each of the HGS Patents was a final agency action that is reviewable by a district court in accordance with 5 U.S.C. § 704.

166. HGS has adequately exhausted all of its administrative remedies under 35 U.S.C. § 154.

167. In the event the Court determines that HGS may not seek recalculation of PTA for the '189 and '501 patents pursuant to 35 U.S.C. § 154 because it is time barred under 35 U.S.C. § 154(b)(4)(A), HGS will be left with no adequate remedy at law.

168. HGS will suffer irreparable injury if Defendant is not directed to recalculate PTA for each of the HGS Patents in accordance with *Wyeth*.

169. An order directing Defendant to recalculate PTA for each of the HGS Patents in accordance with *Wyeth* would not substantially injure any other interested parties, and the public interest will be furthered by a recalculation of PTA for each of the HGS Patents that is not contrary to law.

#### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff demands judgment against Defendant and respectfully requests that this Court enter Orders:

A. Changing the period of patent term adjustment for the '351 patent from 1,497 days to 1,546 days, and requiring Defendant to extend the term of the '351 patent to reflect the 1,546 day patent term adjustment;

B. Changing the period of patent term adjustment for the '236 patent from 209 days to 478 days, or at least 416 days, and requiring Defendant to extend the term of the '236 patent to reflect the 478 day, or at least 416 day, patent term adjustment;

C. Changing the period of patent term adjustment for the '189 patent from 271 days to 399 days and requiring Defendant to extend the term of the '189 patent to reflect the 399 day patent term adjustment;



D. Changing the period of patent term adjustment for the '501 patent from 754 days to 1,135 days and requiring Defendant to extend the term of the '501 patent to reflect the 1,135 day patent term adjustment

E. Granting such other and further relief as the nature of the case may admit or require and as may be just and equitable.

Respectfully submitted,

Dated: July 20, 2010

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